



BARDA INDUSTRY DAY 2019

Addressing the Failing Commercial Market for New Antimicrobial Products

Dr. Rick Bright
October 16, 2019

October 15-16, 2019 | Washington, D.C.

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The BARDA Model

BARDA develops and makes available medical countermeasures (**MCMs**) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.

BARDA's Model has been key to building out a robust R&D Pipeline and obtaining product Approvals



...But BARDA is missing these same key ingredients to support the Commercial Market for dual-utility National Security products:

- ☐ Clear Mandate
- ☐ Flexible Nimble Authorities
- ☐ Dedicated Funding

Yesterday's Antibacterial R&D Program Successes

3 FDA Approvals



4 OTA Partnerships



Diverse R&D Portfolio

ACHAOGEN



TETRA PHASE
PHARMACEUTICALS



AtoxBio











...Are today's Commercial Market Sustainment Liabilities



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This is a Problem...

Because our goal is ensuring a Continuum of Care

	Chlorine	Dyspnea	Lung injury	Opportunistic infection	Persistent infection	Sepsis
	Sulfur Mustard	Blistering	Cellulitis	Opportunistic infection	Systemic infection	Sepsis
	Burns	Blistering	Skin sloughing	Opportunistic infection	Systemic infection	Sepsis
	Acute Radiation	Neutropenia	Immune ablation	Poor wound healing	Systemic infection	Sepsis
	Anthrax	Pneumonia	Disruption of gut flora	Opportunistic infection	Persistent infection	Sepsis
	Influenza	Fever	Congestion	Opportunistic infection	Systemic infection	Sepsis
	Ebola	Fever	Vomiting/diarrhea	Bleeding	Systemic infection	Sepsis
	Smallpox	Fever	Extensive rash/pustules	Opportunistic infection	Systemic infection	Sepsis

A diverse Antimicrobial Commercial Market ensures that no patient is left behind!

Antibiotics needed

BRIEF

Achaogen files for bankruptcy protection, seeks asset sale

“BARDA simply cannot continue to provide non-dilutive investment, only to have companies collapse and their newly minted antibiotics shelved or lost completely”

EDITOR'S PICK | 3,775 views | May 10, 2019, 11:41am

Forbes

Building New Models To Support The Ailing Antibiotics Market



The Lab Bench Contributor @

Science

Perspectives from the cutting edge of science

GUEST POST WRITTEN BY

Dr. Rick Bright

Rick Bright is director of BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services



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Lessons Learned from Ongoing Market Collapse

Achaogen: An Expensive Lesson

- HHS provided push incentives to Achaogen
- Earlier this year, Achaogen sold their assets at auction for \$16M, despite a \$200M HHS investment
- Impact on national security posture and access to these novel antibiotics

Current Market Conditions

Deadly Superbugs Win as Wall Street Flees
Makers of Antibiotics

By Robert Langrish
June 17, 2019 11:00 AM

November 29, 2018 09:36 AM EST | Amber Tong | RSD

BRIEF
Achaogen files for bankruptcy protection, seeks asset sale

Low sales, high cost: Melinta slashes HQ research staff as it struggles to grow antibiotics revenue

Spero Announces \$10 Million Registered Direct Offering of Common Stock

June 13, 2019



TETRAPHASE
PHARMACEUTICALS

Tetraphase Pharmaceuticals Announces Corporate Reorganization Aimed at Maximizing XERAVA™ (Eravacycline) Commercial Opportunity

U.S. Taxpayers Fund Antibiotics for China as Industry Flails

Posted Aug. 9, 2019, 3:20 PM



Tetraphase Pharmaceuticals Announces Reverse Stock Split

September 26, 2019

"Antibiotic R&D Companies Down 49-87% Last Twelve Months"

Takeaways

- More companies will go bankrupt in **1-3 months (updated)**
- Collapse of commercial market impacting R&D companies access to capital. **CARB-X forced to decrease cost share requirement by 3X**
- Additional push incentives will not fix this problem

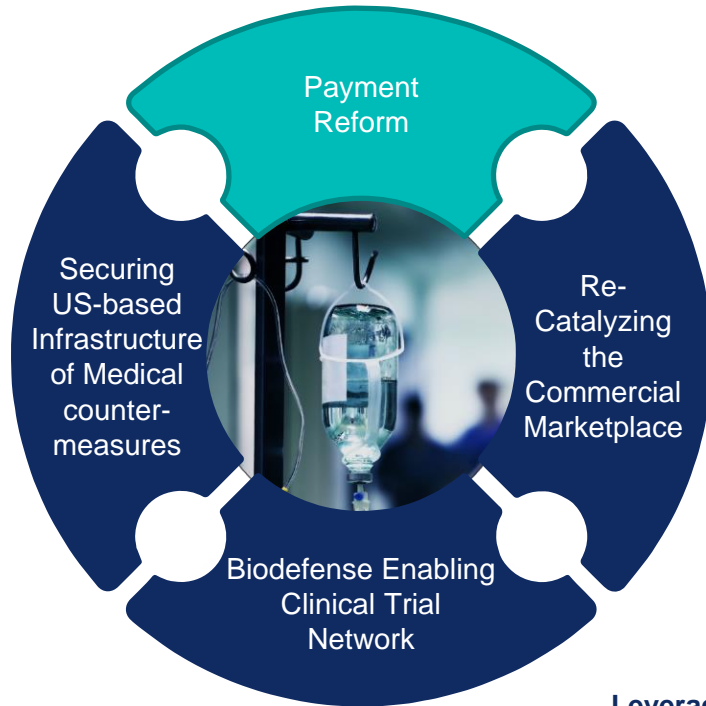


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Proposed Antimicrobial Market Strengthening Initiative



Goals

Work with other HHS and industry partners to identify, influence and implement antimicrobial market strengthening initiatives that catalyze re-investment into the antimicrobial space, rewards innovation, and improves value-based outcomes necessary to address the national health security threat posed by antimicrobial-resistant infections

Leveraging 3rd Party Assessments

Payment Modeling

Plan Validation

Business Assessments



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October 15-16, 2019

Catalyze Health Security



Panel: Current State of Antimicrobial Commercial Market and the Impact on the R&D Pipeline



Mike McGuire,
Melinta Therapeutics



Amanda Jezek,
IDSA



Kathryn Bell,
ASPR Senior Policy
Advisor



Ramani Varanasi
X-Biotix Therapeutics



Robert Horne
Leavitt Partners

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("FedBizOpps")

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www.phe.gov/BARDA

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